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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,677	10/15/2003	Peter Rohdcwald	103265-48964	7043
35437	7590	11/13/2007	EXAMINER	
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO 666 THIRD AVENUE NEW YORK, NY 10017			SCHLIENTZ, NATHAN W	
ART UNIT		PAPER NUMBER		
1616				
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11/13/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,677	ROHDEWALD ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 September 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 7-10 and 16-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 7-10 and 16-23 is/are rejected.

7) Claim(s) 7 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application
6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 September 2007 has been entered.

Status of Claims

Claims 11-15 have been cancelled, claim 7 has been amended, and claims 16-23 have been newly added in an amendment filed 11 September 2007. As a result, claims 7-10 and 16-23 are pending and thus are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

1. The rejection of claims 7 and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,565,851 in view of U.S. Patent Application Publication 2003/0064123 (hereinafter Thompson) is hereby **withdrawn** by the examiner in light of the aforementioned amendment to claim 7, wherein the instant claim is drawn to a method of increasing fertility, which is not

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claimed by the '851 patent nor taught by Thompson, and the aforementioned canceling of claim 12.

2. The provisional rejection of claims 7-15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-13 and 15-18 of copending Application No. 11/054,742 in view of Thompson is hereby **withdrawn** by the examiner in light of the aforementioned amendment to claim 7, wherein the instant claim is drawn to a method of increasing fertility, which is not claimed by the '851 patent nor taught by Thompson, and the aforementioned canceling of claims 11-15.

3. The rejection of claims 7-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the specification does not provide a definition for "attaining enhanced sexual wellness" is hereby **withdrawn** by the examiner in light of the aforementioned claim amendments to claims 7-10, wherein the instant claims deleted the terminology "attaining enhanced sexual wellness", in favor of increasing fertility, and the cancellation of claims 11-14.

4. The rejection of claims 7-14 under 35 U.S.C. 103(a) as being unpatentable over WO 00/00212 (hereinafter Shell et al.) in view of Thompson is hereby **withdrawn** by the examiner in light of the aforementioned claim amendments to claims 7-10, wherein the instant claims are drawn to a method of increasing fertility, which is not taught by Shell et al. nor Thompson, and the cancellation of claims 11-14.

5. The rejection of claims 7-14 under 35 U.S.C. 103(a) as being unpatentable over WO 00/00212 (hereinafter Shell et al.) in view of U.S. Patent No. 4,835,147 (hereinafter Roberts) is hereby **withdrawn** by the examiner in light of the aforementioned claim

amendments to claims 7-10, wherein the instant claims are drawn to a method of increasing fertility, which is not taught by Shell et al. nor Roberts, and the cancellation of claims 11-14.

6. The rejection of claims 7-14 under 35 U.S.C. 103(a) as being unpatentable over DE 198 45 314 (hereinafter Rohdewald) in view of Thompson is hereby **withdrawn** by the examiner in light of the aforementioned claim amendments to claims 7-10, wherein the instant claims are drawn to a method of increasing fertility, which is not taught by Rohdewald nor Thompson, and the cancellation of claims 11-14.

7. The rejection of claims 7-14 under 35 U.S.C. 103(a) as being unpatentable over DE 198 45 314 (hereinafter Rohdewald) in view of Roberts is hereby **withdrawn** by the examiner in light of the aforementioned claim amendments to claims 7-10, wherein the instant claims are drawn to a method of increasing fertility, which is not taught by Rohdewald nor Roberts, and the cancellation of claims 11-14.

Response to Arguments

Applicant's arguments with respect to the rejections in the Office Action mailed 9 November 2006 have been fully considered. The rejections that were rejected are discussed above, in light of the aforementioned amendment to claim 7 and the cancellation of claims 11-15. Therefore, the new grounds of rejections are presented herein below.

Claim Objections

1. Claim 7 is objected to because of the following informalities: the last line states, "to to increase fertility by an end of the period of time". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 18 recites, "A method of increasing *sperm quality...*", however, the instant specification does not provide an explicit definition, description, or explanation for the meaning of *sperm quality*. The instant specification merely states, "the *quality of sperm* was significantly improved and 44% of the couples achieved pregnancy." It is not clear if the improved "sperm quality" is an increase in the number of sperm produced, an increase in sperm motility, an improvement in the percentage of mobile vs. immobile sperm, etc., because the instant specification does not define "sperm quality". Claims 19-23 are dependent from claim 18 and include all of the limitations of the independent claim, and are therefore likewise

rejected as failing to comply with the written description requirement. Appropriate correction is required.

2. Claims 7-10 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating erectile dysfunction, does not reasonably provide enablement for increasing fertility. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the nature of the invention
- 2) the state of the prior art
- 3) the relative skill of those in the art
- 4) the predictability of the art
- 5) the breadth of the claims
- 6) the amount of direction or guidance provided
- 7) the presence or absence of working examples
- 8) the quantity of experimentation necessary

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

The claimed invention relates to a method of increasing fertility by administering a sex hormone, a source of arginine, and proanthocyanidins over a period of time.

The state of the prior art

Fertility is defined as the ability to conceive and have children.¹ Fertility depends on many factors including the production of a sufficient number of healthy sperm by the male, delivery of the sperm into the vagina, passage of the sperm through the uterus up into the fallopian tubes, and penetration of a normal ovum (egg) by one of the sperm. A successful pregnancy also requires that the fertilized ovum become implanted in the lining of the uterus.

The breadth of the claims

The claims are very broad in that they are drawn to a method of increasing fertility in any patient, including men and women.

The presence or absence of working examples

The instant specification provides one example wherein 50 male subjects suffering from erectile dysfunction (only 10% reported normal erections) were administered pycnogenol, L-arginine, and testosterone undecanoate over a period of 12 months. The erectile dysfunction was treated with up to 76% of the men experiencing a normal erectile function. As a result, 44% of the couples achieved pregnancy.

The quantity of experimentation necessary

In order to determine the ability of the claimed method to treat all patients suffering from infertility, not just men suffering from erectile dysfunction, would require undue experimentation. As mentioned above, fertility depends on many factors, some of which are effected by sperm count, sperm motility, ovulation, implantation of a

¹ Definition of Fertility, <http://www.medterms.com/script/main/art.asp?articlekey=3412>, 7 November 2007.

fertilized egg in the uterus, and formation of the placenta. Any number of complications can cause infertility, such as pelvic infection, endometriosis, immobile sperm, etc., which will not be treated by merely reversing the effects of erectile dysfunction. Thus, a person of ordinary skill in the art would be required to determine the ability of administering a sex hormone, a source of arginine, and proanthocyanidins over a period of time to increase fertility in instances wherein infertility is not a result of erectile dysfunction.

Therefore, for the aforementioned reasons, the Applicant is enabled for treating erectile dysfunction, but is not reasonably enabled for increasing fertility.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nathan W. Schlientz
Patent Examiner
Technology Center 1600
Group Art Unit 1616


SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sabiha Qazi
Primary Patent Examiner
Technology Center 1600
Group Art Unit 1616